

# IDEAS: DU PROJET À SON IMPLÉMENTATION

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# GRANT APPLICATION

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# IDEAS: summary

- Marie Curie Initial Training Networks (ITN) Call: (2<sup>nd</sup> attempt)
- “Improving Design, Evaluation and Analysis of early drug development Studies (IDEAS)”
  - PI: T. Jaki (Lancaster University) & Dr Franz König (Vienna University)
  - Network of students in **clinical biostatistics**
  - Around a common stat technic (adaptive designs)
    - that applies at the various stages of clinical development of a new agent
      - Dose finding
      - Phase II/ III trials
      - Arm selection trials etc.
    - Is a very active field of research in biostatistics
    - Is strongly debated by the regulatory authorities
      - interest from the academia, the pharma, the regulatory agencies

# IDEAS: summary

- 7 European beneficiaries
  - 6 countries
  - 5 academia (Lancaster, Vienna, Bremen, Torino Universities and INSERM)
  - 3 pharma companies (Bayer, Novartis, Jansen)
- 14 phd projects
- About 260 000€ / student
  - about 160 k€ for salary (per month 3.3k€ + 600€ for mobility + 500€ if married)

**Ask for more than 1 phd per beneficiary!**

Associate other researchers from your unit

# Scientific content (phd research projects)

- Not central
  - Due to space restriction, each thesis description is minimal (half a page)
  - Not really standardized
  - For each topic: include
    - external advisors (clinicians in our setting)
    - A reviewer chosen among the partners
  - No need for specific interactions between topics
- But should be clear and concise enough to convince reviewers
  - Our first attempt was a failure due to insufficient details (but still high grades >70%)
- At least some beneficiaries should be top-quality to improve credibility of the overall project

# Implementation: Building the network

- **Key aspect**
- **The objective is that students finish their phd with strong connections in several countries**
- It must be made clear
  - How students will interact
  - How external reviewers will be involved
  - How the team building will be obtained (courses, exchanges)
  - The tools that will be implemented to help in the creation of this network
    - Twitter account
    - You tube
    - Website and so forth

# Implementation: Building the network

- Content of courses should include
  - High level trainings  
Emphasize the progression in the level of the courses
    - from initiation that will help building common background
    - to more advanced teaching
  - Team building sessions to help students from various backgrounds to get involved
  - Assess the feasibility and timelines
- **The experience of a University is central**
  - To help designing the sequence of teachings
  - To convince the reviewers of the quality of the teaching
  - If the team leader is used to organize courses, it helps!

# Implementation: Interaction private /public

- In IDEAS: PhD are supervised by stat from pharma companies
  - Balanced relationship
  - All students will have the possibility to visit both private and public structures (but not mandatory)
- Various professional perspectives for students



# GRANT IMPLEMENTATION

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The hard day work

# Common difficulties

- Private and Public beneficiaries do not have the same constraints!
  - be careful with the eligible costs
- Various countries do not have the same PhD rules
  - find a way to standardize the phd process
  - **discuss upfront with the Ecole doctorale**
  - you must have good relationships with your university!
- **Consortium agreement requires the help of specialized people**

# Common difficulties

- Finding a student is not straightforward
  - Selection in March (the timelines in England)
    - may not match the French University process
  - Only students who you do not know
  - Applications from all over the world
    - **lack of support from the French University to identify good foreign universities**
    - no documents or explanations in English
  - Do not do the interviews alone!

# Troubles with the French system

- The French *millefeuille* is hardly understandable abroad
- Xavier Paoletti
  - Gustave Roussy Cancer Campus
  - INSERM U1018
  - Paris Saclay University
- The student will be
  - Hired and paid by INSERM
  - Registered to the Paris Saclay University  
go to the Paris South medical faculty
  - “housed” by Gustave Roussy Cancer Campus
- **EC is lost** (the foreign students too...)!

# INSERM a suspect organization?

*Email from the EC:*

- The project officer has now requested another piece of clarification regarding the status of INSERM and the Institute Gustave Roussy.
- **I took into consideration the explanation you received from Dr Paoletti regarding the double affiliation he has with Gustave Roussy Hospital and INSERM (email attached).**

I have one more question: **Is the hospital a part of the Gustave Roussy Institute or a different legal entity?** Could you please send me a formal confirmation signed by the legal authorised representative of Gustave Roussy stating that this legal entity is not hiring the MSCA researchers (please inform them that the researcher under MSCA have a classical employment contract).

# Behind a computer, there is always someone!

- INSERM ADR accepted to contract even if the amendment was not signed yet by both parties  
*Thanks a lot 😊*
- Direct connection between the ADR and the coordinator is now swift and efficient
- Absence of a unique interlocutor is a real issue
- **Having a central bureau at inserm** for all these grants would help mutualizing experience
- **Person to person contacts are mandatory!**

# Conclusions

- Importance of detailing all aspects of organisation
- Network of researchers is important but this is not necessary to demonstrate that it is already operational
- An efficient administration is mandatory
- Curie Institut was highly efficient with
  - A central office that centralizes all documents and requests and dispatches them to the right persons (Patents, legal, direction etc.)
  - A strong knowledge of people at EC
  - A large experience of issues, expected answers, process etc.
- Unfortunately, too few institutes have this organisation  
→ too many actions have still to be done to link the coordinator with the administration
- Time consuming!